UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,002	03/19/2004	Tetsuya Ishizuka	250594US0CONT	8128

22850 7590 11/28/2006

C. IRVIN MCCLELLAND
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,002	ISHIZUKA ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8, 10-14, 16-20* is/are rejected.

7)☒ Claim(s) *9 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 3/19/2004 has been entered. Claims 8-20 are pending. The response filed June 30, 2006 to the Office action mailed 5/31/2006 has been entered.

The Office action mailed 8/25/06 is vacated in light of the preliminary amendment filed 3/19/04.

Election/Restrictions

1. Applicant's election with traverse of the invention of the combination of SEQ IN NO: 1, 15, 27 and 34 for amplifying RNA derived from HIV-1 in the reply filed on June 30, 2006 is acknowledged. The traversal is on the ground(s) that the Office has not provided any reasons or examples to support that the species are indeed patentably distinct and there is no a serious burden to search all of the claims, further, if the elected species are found allowable, the Office should expand its search to the non-elected species. However, the Office action mailed 5/31/2006 is a restriction requirement for distinct inventions and is not a species election. Moreover the argument made in the response is not found persuasive because there is no specific argument made regarding the elected invention of the combination of the nucleic acid sequences, which are not patentably distinct over the other inventions of using the combinations of nucleic acid sequences as primers, and therefore, it is a serious burden to search several inventions at the same time.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 6-20 are objected to because of the following informalities: claims 6-20 contain non-elected nucleic acid sequences. Appropriate correction is required to amend the claims to

delete the non-elected nucleic acid sequences or cancel the claims, which do not have the elected nucleic acid sequences.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8, 10, 14-16 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 8 and 14 are vague and indefinite because of the phrase "a sequence homologous to the specific sequence" recited in claims 8 and 14. It is unclear what is the definition for the phrase "a sequence homologous to". Clarification is required.

b. Claims 10 and 16 are vague and indefinite because of the parenthesis used in the claims 10 and 16. It is unclear whether or not the languages in the parenthesis are used in the limitations for claiming the invention. Clarification is required.

c. Claims 8 and 14 are vague and indefinite because of the phrase "denuding" in claim 8 and 14. It is unclear what is the definition used herein. Clarification is required.

d. Claims 18-20 are vague and indefinite because of the phrase "can bind to" recited in claim 18. It is unclear whether or not the oligonucleotide probe is really binding to the RNA transcript.

e. Claims 18-20 are vague and indefinite because of the phrase "the reaction solution" recited in line 3 of claim 18, which has no antecedent basis.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 6-8, 10-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton (Nature, 1991, vol. 350(7), pg. 91-92) in view of Pavlakis et al. (6,174,666, issued Jan. 16, 2001) and Buck et al. (Bio technique, 1999, Vol. 27(3)).

Compton discloses nucleic acid sequence-based amplification (NASBA). The NASBA comprising the same method steps as recited in claims 6-8, 10-14, 16-17 (See pg. 91, pg. Column 1, second and third paragraphs, fig. 1).

Compton does not disclose the specific nucleic acid sequences as recited in claims 1 and 12 used as the first and the second primers in the instant method for amplifying HIV-1 RNA and detecting HIV-1 RNA.

Pavlakis et al. disclose a method and construct which are exemplified by the mutation of a Human Immunodeficiency Virus-1 Rev-dependent gag gene to a Re-independent gag gene (See the Abstract). In Fig. 4, nucleotide sequence of the HIV-1 p17 gag region is disclosed with all mutants underlined (See column 7, lines 60-64). Nucleic acid sequences listed in Table 1 are corresponding to nucleotides in FIG. 4. (See column 28, lines 54-67). SEQ ID NO: 2 in Table 1 comprises SEQ ID NOs: 15 and 27 used as primers in the instant invention and SEQ ID NO: 3 in Table 1 comprises SEQ ID NO: 1 used as primer in the instant invention (See the attached nucleic acid search report).

Pavlakis et al. do not disclose these nucleic acid segments, which are selected as primers for amplifying RNA derived from HIV-1.

Buck et al. disclose the strategies for sequencing primer selection and parameter preferred for selecting primers to be used in PCR (See pg. 528,column 1, Abstract), for example, the preferred primer is 18-24 nucleotides in length, 39%-58% of G+C in content and a melting temperature of 53^0C-65^0C (See pg. 529, Table 1).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply NASBA for amplifying and detecting HIV-1 RNA as taught by Compton because as indicated by Compton, NASBA offers a simple and rapid nucleic acid amplification at a continuous and isothermal process without specialized equipment (See pg. 91, column 1, second paragraph) with high fidelity process (See pg. 91, column 3, second paragraph and third paragraph) and better specificity of the detection of HIV (See pg. 92, column 1, first and third paragraph). It would have been prima facie obvious to apply NASBA for amplifying and detecting HIV-1 RNA.

One of ordinary skill in the art at the time of the instant invention would have also been motivated to select nucleic acid sequences used as primers for amplifying RNA derived from HIV-1 from a disclosed nucleotide sequence of the HIV-1 p17 gag region by Pavlakis et al. because Buck et al. disclose the strategies to select PCR primers. It would have been prima facie obvious to select SEQ ID NO: 1, 15 and 27 claimed as primers for amplifying RNA derived from HIV.

7. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton (Nature, 1991, vol. 350(7), pg. 91-92) in view of Pavlakis et al. (6,174,666, issued Jan. 16, 2001) and Buck et al. (Bio technique, 1999, Vol. 27(3)) as applied to claims 6-8. 10-14, and 16-17 above, and further in view of Miller (5,374,524, issued December 20, 1994)

The teachings of Compton, Pavlakis et al. and Buck et al. are set forth in section 6 above. None of the references discloses that SEQ IN NO: 34 is used as probe for hybridizing with at least part of the RNA transcript and the probe is labeled with a fluorescent dye.

Miller discloses the amplification of target nucleic acid HIV by PCR in which primer B is used as one of the primers. Primer B has the same nucleotide sequence as the sequence of SEQ ID NO: 34 (See column 9, lines 17-25), which is used as an oligonucleotide probe in the instant claim 20. Miller also discloses a reporter probe for the detection of the target HIV-I DNA (See the Abstract) via hybridization in which the probe is labeled with fluorophores (See column 5, lines 58-64).

One of ordinary skill in the art at the time of the instant invention would have been motivated to use primer B of Miller for hybridizing with at least part of the RNA transcript because the primer is a probe which has the same specificity as the probe, and primer B of Miller

is specific for the target nucleic acid sequence of gag p17 region (See column 9, lines 17-25). Moreover, Miller discloses the report probe labeled with fluorophres used for the hybridization detection of the target (See column 5, lines 58-64). It would have been prima facie obvious to apply the primer B (SEQ ID NO: 34) as probe for hybridizing with at least part of the RNA transcript.

8. U.S. patent NO. 7,049,067 issued May 23, 2006 is made of record as reference of interest because the reference discloses an oligonucleotide, which is useful for detection of an RNA derived from HIV-1 and in which the primers used in the method have overlapping sequences with the primers of the instant invention (See column 3, line 48).

Summary

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung J.T.
November 25, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
11/27/06